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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,864	10/15/2001	Henryk Dudek	CIBT-P01-104	3719

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EXAMINER

HOWARD, ZACHARY C

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/977,864	<b>Applicant(s)</b> DUDEK ET AL.	
	<b>Examiner</b> Zachary C. Howard	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Status of Application, Amendments and/or Claims***

Claims 1-22 are pending.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, 17, 18 and 21-22, in so far as they are drawn to a method of inhibiting unwanted growth, proliferation, or survival of a cell expressing a *gli* gene or a *hedgehog* gene, classified in class 435, subclass 375, for example.
- II. Claims 10-13 and 17-20, in so far as they are drawn to a method for determining a treatment protocol or determining the likelihood cancer will develop in a tissue, comprising assaying *gli* gene expression in a sample, classified in class 435, subclass 6.
- III. Claims 14 and 16-18, in so far as they are drawn to a method of stimulating surfactant production in a lung cell by contact with a hedgehog antagonist, classified in class 435, subclass 4, for example.
- IV. Claim 15 and 16-18, in so far as they are drawn to a method of stimulating lamellated body formation in a lung cell by contact with a hedgehog antagonist, classified in class 435, subclass 4, for example.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I-IV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of inhibition of unwanted growth, proliferation or survival of a cell, which is not required by any of the other

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Inventions. Invention II requires search and consideration of determination of a treatment protocol for patient having a sample in which *gli* is overexpressed, which is not required by any of the other Inventions. Invention III requires search and consideration of stimulation of surfactant production in a lung cell, which is not required by any of the other Inventions. Invention IV requires search and consideration of stimulation of lamellated body formation in a lung cell, which is not required by any of the other Inventions.

Furthermore, the distinct steps and ingredients of the methods require separate and distinct searches. The inventions of Groups I-IV have a separate status in the art as shown by their different classifications and separate, non-coextensive search requirements. As such it would be burdensome to search the inventions of Groups I-IV together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and/or divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### Election of species

In addition to the above restriction requirement, a further election of species is required as follows:

a) Applicant must elect one of the following patentably distinct species of unwanted growth, proliferation, or survival of a cell in the claimed invention: urogenital

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cancer, ovary-associated cancer, uterus-associated cancer, muscle-associated cancer, bladder-associated cancer, colon-associated cancer, kidney-associated cancer, pancreas-associated cancer, liver-associated cancer, inferior ductal breast-associated carcinoma, inferior lobular breast-associated carcinoma, intraductal breast-associated carcinoma, medullary breast-associated carcinoma, tubular breast-associated carcinoma, another species of breast-associated carcinoma, lung-associated adenocarcinoma, broncho-alveolar adenocarcinoma, small cell carcinoma, another species of lung-associated carcinoma, prostate-associated adenocarcinoma, another species of prostate-associated cancer, or benign prostatic hyperplasia.

Each form of unwanted growth, proliferation, or survival of a cell is considered to constitute a patentably distinct species because each form has a different etiology, diagnosis, location in the body, and effective treatment, and requires a separate search. Search of more than a single species would constitute an undue burden on the Office.

Applicant is required under 35 U.S.C 121 to elect one single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 3 and 5 are generic.

b) Applicant must also elect one of the following patentably distinct species of hedgehog antagonist in the claimed invention: *hedgehog* antibody, *patched* antibody, *smoothened* antibody, mutant hedgehog protein, antisense nucleic acid, RNAi construct, ribozyme, cyclopamine, compound A, tomatidine, jervine, AY9944, triparanol, or compound B.

Each form of hedgehog antagonist is considered to constitute a patentably distinct species because each antagonist has a separate structure, and requires a separate search. Search of more than a single species would constitute an undue burden on the Office.

Applicant is required under 35 U.S.C 121 to elect one single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3 and 17 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*Bridget C. Bunner*

**BRIDGET BUNNER  
PATENT EXAMINER**